DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 13-21-01
Publication Date 13-36-01
Certifier Sklese

Food and Drug Administration

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Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory

Committee: Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 10, 2002, from 9:30 a.m. to 5 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Hany W. Demian, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12521. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on premarket approval application (PMA) for a spinal fusion cage with a growth factor soaked in a collagen sponge intended for use to treat lumbar degenerative disc disease. Background information, including the agenda and questions for the committee, will be available to the public on January 9, 2002, on the Internet at http://www.fda.gov/cdrh/panelmtg.html.

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Procedure: On January 10, 2002, from 9:30 a.m. to 1 p.m., and from 2 p.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 4, 2002. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m. on January 10, 2002. Near the end of the committee deliberations for the PMA, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 4, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Presentation of Data: On January 10, 2002, from 1 p.m. to 2 p.m., the meeting will be closed to the public to permit the committee to discuss and review trade secret and/or confidential commercial information presented by a sponsor (5 U.S.C. 552b(c)(4)).

FDA regrets that it was unable to publish this notice 15 days prior to the January 10, 2002, Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated:

12-18-01

December 18, 2001.

Linda A. Suydam, Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-S

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